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Methods of Surveillance for HIV Infection at U.S. Sentinel Hospitals

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Synopsis

The U.S. sentinel hospital surveillance system for human immunodeficiency virus (HIV) infection includes approximately 40 short-stay hospitals located in 31 metropolitan areas in the United States and Puerto Rico. Several hospitals began testing in late 1986, and

additional sentinel hospitals have since been recruited. At each sentinel hospital, anonymous, unlinked testing for antibody to HIV is conducted monthly on 300 blood specimens, selected systematically and stratified by age of the patient. Specimens are excluded from patients whose reason for hospital visit on that occasion was for a medical condition associated with HIV infection or with risk factors for HIV infection, in order to limit the expected overrepresentation of HIV-infected persons among hospital patients compared with the general catchment population of the hospital.

The incidence of acquired immunodeficiency syndrome (AIDS) in metropolitan areas with sentinel hospitals has been approximately twice the incidence of AIDS in the entire United States. However, while absolute levels of HIV seroprevalence should therefore be interpreted with caution, trends in the age-, sex-, and race-specific HIV seroprevalence at sentinel hospitals likely reflect trends in the communities served by the hospitals.

Although concentrated in areas disproportionately affected by AIDS, sentinel hospitals will contribute seroprevalence data over time that reflect the impact of HIV infection across all age and behavioral risk groups. Sentinel hospitals will also constitute a key surveillance system to help integrate the age group-specific and risk group-specific findings from other activities in the CDC family of seroprevalence surveys.

THE SENTINEL HOSPITAL surveillance system for human immunodeficiency virus (HIV) infection is one of a family of ongoing, sentinel serologic surveillance projects of the Public Health Service (1, 2). The first sentinel hospital began sampling in late 1986, and additional hospitals have been recruited since that time. By September 1989, a total of 40 acute care hospitals were participating in the sentinel hospital network. This report reviews the objectives, survey design issues, and the methods of sentinel hospital surveillance and dis-

cusses briefly how these methods influence the interpretation of findings.

Objectives

Trend analysis. The principal objectives of the sentinel hospital surveillance system are to (a) establish a stable, systematic mechanism for sampling HIV seroprevalence in the catchment populations of a group of acute care (short-stay) hospitals, and (b) follow trends over time in

HIV seroprevalence in a set of sentinel communities, to contribute to monitoring the epidemic of HIV and acquired immunodeficiency syndrome (AIDS).

Demographic distribution of HIV infection. Another objective is to assess demographic factors associated with HIV infection. This includes the variation of HIV seroprevalence by age, sex, and race both within the patient population of each hospital and across the sample of 40 hospitals.

Survey Design Issues

The HIV seroprevalence survey in sentinel hospitals was designed to meet the stated objectives while taking into account the following ethical and epidemiologic considerations:

Ethics. Ethical concerns and considerations are paramount to understanding why this surveillance system was undertaken as well as how it was implemented. The technique of anonymous, unlinked testing for HIV infection was developed to meet the unique epidemiologic needs and practical constraints introduced by the AIDS epidemic (1, 3). The approach to anonymous, unlinked seroprevalence testing that has developed at CDC from balancing these considerations is based on two principles: (a) that no extra demands of even a minor sort be imposed upon patients who have not given informed consent, such as drawing extra blood during a venipuncture performed for clinical reasons or asking for additional information that would not have been sought had the study not been taking place; and (b) that HIV antibody testing take place only after each specimen has been stripped of all information that could identify its source, not only directly but also indirectly by linkage to any other extant information.

These principles limit anonymous, unlinked serosurveys to sites where blood is routinely drawn for other purposes and limit the information available for analysis. However, this testing strategy uniquely avoids differential response bias—the tendency of persons at different perceived levels of risk to differentially decline participation—that is the dominant issue complicating efforts to measure prevalence of HIV infection (4, 5).

Chronicity of HIV infection. The long latency from HIV infection to symptomatic illness introduces a potential major bias in data used to monitor trends in HIV seroprevalence at sentinel hospitals. Persons already infected with HIV before sentinel hospital surveillance began can be expected progressively to become ill and increasingly to require visits to the hos-

'The 40 sentinel hospitals are located in 31 metropolitan areas in the United States and Puerto Rico. One sentinel hospital may actually consist of two or more collaborating hospitals to ensure a sufficient number of specimens from both pediatric and adult patients.'

pital in subsequent years of surveillance. An increasing proportion of hospital patients with HIV infection might therefore be expected over time even if no new HIV infections were to occur in the catchment population of the hospital. To minimize this potential bias, eligibility criteria for inclusion in the sentinel hospital surveillance population exclude specimens from persons whose reason for visit is associated with HIV infection. By excluding such specimens, overrepresentation of HIV-infected persons among hospital patients (resulting from the need among HIV-infected persons for additional medical services) can be minimized. Moreover, the sentinel hospitals' seroprevalence rates over time will be less dependent on the progression of HIV-associated illness in the community served by the hospital, an important consideration in trend analysis.

Repeated hospital visits. Approximately 20 percent of visits to acute care hospitals in the United States in 1988 were repeat visits (6). Also, blood may be drawn from a patient on several occasions during the same hospital admission. Since the sentinel hospital surveillance system was designed principally to estimate annual trends in seropositivity, specimens are excluded from patients whose specimens have already been tested within the calendar year.

Geographic distribution of HIV. The highly focal distribution of AIDS in the United States (7) suggests that the distribution of HIV infection also varies by demographic and behavioral subgroup and by geographic area. Seroprevalence data from the screening of civilian applicants for military service (8) and from childbearing women (9, 10) support this belief. The focal nature of the HIV epidemic reinforces the importance of establishing surveillance in hospitals from a wide range of epidemiologic settings and cautions against overinterpretation of findings not replicated at more than a small number of hospitals.

Table 1. Location of U.S. sentinel hospitals and AIDS cases reported in 1988

Metropolitan area	Number of sentinel hospitals	Reported AIDS cases (1988)	Population (est. 1988)	Reported AIDS cases per 100,000
Albany-Schenectady-Troy, NY.....	1	72	847,725	8.5
Albuquerque, NM.....	1	28	501,430	5.6
Ann Arbor, MI.....	1	18	270,317	6.7
Baltimore, MD.....	2	313	2,327,038	13.5
Boston, MA.....	1	498	3,746,244	13.3
Chicago, IL.....	2	868	6,212,801	14.0
Cleveland, OH.....	1	129	1,846,843	7.0
Dallas, TX.....	1	545	2,534,336	21.5
Denver, CO.....	1	257	1,667,854	15.4
Detroit, MI.....	1	324	4,375,086	7.4
Honolulu, HI.....	2	87	842,287	10.3
Jacksonville, FL.....	1	162	899,226	18.0
Kansas City, MO-KS.....	1	244	1,566,687	15.6
Los Angeles-Long Beach, CA.....	3	1,937	8,651,592	22.4
Memphis, TN-AR-MS.....	1	103	982,568	10.5
Miami-Hialeah, FL.....	1	704	1,811,496	38.9
Minneapolis-St. Paul, MN-WI.....	1	149	2,371,411	6.3
New Orleans, LA.....	1	242	1,327,135	18.2
New York, NY.....	3	5,977	8,538,593	70.0
Newark, NJ.....	2	1,071	1,897,933	56.4
Omaha, NE-LA.....	1	36	620,552	5.8
Phoenix, AZ.....	1	222	2,045,691	10.9
Richmond-Petersburg, VA.....	1	59	835,956	7.1
St. Louis, MO-IL.....	1	168	2,475,664	6.8
Salt Lake City-Ogden, UT.....	1	69	1,077,372	6.4
San Jose, CA.....	1	162	1,423,615	11.4
San Juan, PR.....	2	735	1,860,376	39.5
Sarasota, FL.....	1	36	260,654	13.8
Seattle, WA.....	2	260	1,823,822	14.3
Washington, DC-MD-VA.....	1	809	3,711,651	21.8
All areas with sentinel hospitals.....	40	16,284	69,353,955	24.1
All United States.....	40	32,196	245,806,918	13.1

Methods: Selection of Hospitals

Characteristics sought in sentinel hospitals. Features sought in prospective sentinel hospitals included (a) a sufficient volume of patients to generate an adequate number of blood specimens in each of several age-sex categories, (b) a patient population of various racial and socioeconomic strata, and (c) hospital personnel willing and capable of rigorously following the surveillance protocol.

Target metropolitan areas. Sentinel hospitals were recruited in cities that were targeted for initial implementation of the CDC family of seroprevalence surveys (1, 2); these cities are located in all geographic regions of the United States and in areas with varying rates of AIDS cases, so that sentinel monitoring of the HIV epi-

demio would be established in a wide range of epidemiologic settings. Because facilities large enough to accomplish the sentinel hospital sampling protocol are not generally located in rural settings, no sentinel hospitals were recruited from rural areas.

Process of selection. State and local health departments were asked to help recruit sentinel hospitals in target cities. In addition, announcements were placed in nationwide publications. However, it was not possible to secure participation by hospitals in all targeted metropolitan areas, usually because of concerns by hospital administrators about potential adverse publicity. Successful proposals to participate were also received from outside of the original target cities.

Characteristics of hospitals. The 40 sentinel hospitals are located in 31 metropolitan areas in the United States and Puerto Rico (table 1). One sentinel hospital may actually consist of two or more collaborating hospitals to ensure a sufficient number of specimens from both pediatric and adult patients. One crude measure of the geographic bias in the location of sentinel hospitals shows that the aggregate incidence of AIDS in the metropolitan statistical areas (MSAs) with sentinel hospitals is nearly twice that of the United States (table 1).

In addition to location in metropolitan areas with a relatively high incidence of AIDS, sentinel hospitals are much larger, serve a higher proportion of patients insured through Medicaid, are less likely to be investor-owned, and are more likely to be located in the western United States than are U.S. hospitals in general (table 2 and table 3). The combined effect of these potential influences on the observed seroepidemiology of HIV infection in the sentinel hospital surveillance system is not yet clear.

Methods: Selection of Specimens

Specimen collection. At each sentinel hospital, the serum or plasma specimens from inpatients and outpatients remaining after clinical laboratory testing had been completed were systematically collected. At least 0.5 milliter (ml) of serum or plasma is required for adults; 0.15 ml is sufficient for children. Specimens are stored refrigerated at 4° centigrade until subsampling and testing occurs.

Eligibility criteria. The eligibility criteria restricts specimen collection to persons whose current hospital visit is not associated with an increased likelihood of HIV infection compared with other persons in the hospital catchment population. Specimens are excluded if drawn from patients whose admitting diagnosis or reason for the current hospital visit is among the following general groups of ineligible conditions:

Sentinel Hospital Surveillance System Eligibility Criteria

All patients are eligible except those with the following or synonymous conditions reported as the principal reason for hospital visit:

1. All conditions frequently associated with AIDS or with HIV infection, including but not limited to: AIDS, ARC, lymphadenopathy, immune disorder, *Pneumocystis carinii* pneumonia (PCP), toxoplasmosis, cytomegalovirus retinitis, Kaposi's sarcoma, mycobacteriosis (including tuberculosis), herpes zoster, cryptococcal meningitis.

2. Fever, sepsis, suspected sepsis, fever of unknown origin, suspect bone or joint infection, endocarditis, or other systemic febrile illnesses of uncertain etiology.

3. Pneumonia and other acute lower respiratory tract disease, including diagnoses of: PCP, pneumonitis, cough, hemoptysis, bronchitis, respiratory syncytial virus, and so forth. However, asthma, allergic lung disease, and chronic obstructive or restrictive lung disease are not excluded.

4. Diarrhea, chronic diarrhea, *Salmonella* infection, cryptosporidiosis, weight loss, wasting, failure to thrive, and any other acute lower gastrointestinal illness or nutritional complaint often associated with HIV infection.

5. Thrush, *Candida* infection, esophagitis, dysphagia, difficulty swallowing.

6. Drug overdose in patients 13 years of age or older, drug addiction, superficial phlebitis, skin abscess, cellulitis. Alco-

holism and conditions commonly associated with alcohol abuse, including detoxification, any type of hepatitis or liver disease, cirrhosis, ascites, gastrointestinal bleeding, pancreatitis, pancreatotomy, gastritis, gastrectomy.

7. Gunshot or stab wound.

8. Suicide attempt, psychiatric conditions in persons 18 years or older, headache, dementia, encephalopathy, encephalitis, meningitis, brain abscess, or any mental status change (including vague neurologic complaints like "weakness" or "dizziness") except that resulting from head trauma.

9. Any cancer, mass, biopsy, or unspecified pain or pain control. However, patients with chest, back, flank, abdominal, or extremity pain are not excluded. Also, benign prostatic hypertrophy and uterine myomas are not excluded.

10. Bleeding disorder, hemophilia, thrombocytopenia.

11. Any skin disease or rash; any sexually transmitted disease or other genital infection, including pelvic inflammatory disease and prostatitis.

12. Organ transplant or rejection; renal dialysis.

NOTE: These eligibility criteria are applied in close consultation with the Principal Investigator, who in turn remains in close consultation with the Study Director at CDC to resolve questions about eligibility.

1. AIDS or other medical conditions commonly associated with AIDS or with HIV infection.

2. Conditions that might presumptively be expected to occur more frequently among HIV-infected persons, such as diarrhea, pneumonia, most infectious diseases, unexplained fever, neuropsychiatric conditions, and neoplasms.

3. Conditions often associated with medical risk factors (such as hemophilia) or behavioral risk factors (such as drug abuse or sexually transmitted diseases) for HIV infection.

4. Gunshot and knife wounds, conditions associated with lifestyle that have been reported in the past to be associated with higher than expected rates of HIV infection (11). A detailed description of the eligibility criteria is presented in the box on this page.

Prevention of multiple testing of specimens from the same patient. To prevent testing of specimens from the same patient within a calendar year, a file is maintained with an encrypted form of a patient identifier (such as a substring of a hospital medical record number). This file is not linked in any manner to the data file that contains test results; in addition, 10 percent of the encrypted records are for specimens that have not been tested (see subsequent discussion of Random Subsampling). Therefore, even if the identifiers could be recon-

Table 2. Mean and median number of beds, admissions per year, and percentage of patients insured by Medicaid, sentinel hospitals, and all acute care hospitals, in the United States

Characteristic	Sentinel hospitals		All U.S. hospitals ¹	
	Mean	Median	Mean	Median
Number of beds.....	628	506	149	61
Admission per year.....	22,746	21,173	4,433	2,015
Percent of patients insured by Medicaid.....	24	15	10	10

¹Data from American Hospital Association Survey of U.S. Hospitals, 1985.

stituted, the patient associated with a test result could not be determined.

Sample size and stratification. The monthly sentinel hospital sample includes 300 specimens from six age groups: 0-4 years, 40 specimens; 5-14 years, 36 specimens; 15-24 years, 50 specimens; 25-44 years, 100 specimens; 45-64 years, 50 specimens; 65 years or older, 24 specimens. The sample for each age group is divided equally between males and females. Because of this stratified sampling procedure, the monthly sentinel hospital sample of 300 specimens is evenly divided by sex, and the age distribution of the sample is closer to

Table 3. Type of hospital and geographic location of sentinel hospitals and of acute care hospitals in the United States

Characteristic	Sentinel hospitals (N = 40)		All U.S. hospitals (N = 6,531) ¹	
	Number	Percent	Number	Percent
Type:				
Private, not-for-profit	24	60	3,472	53
Government, non-Federal	15	38	1,709	26
Government, Federal	0	0	310	5
Investor-owned	1	2	1,040	16
Geographic location in United States:				
Northeast ²	9	22	1,008	15
Midwest	9	22	1,808	28
South	10	25	2,461	38
West	12	40	1,254	19

¹Data from American Hospital Association Survey of U.S. Hospitals, 1985.

²Hospitals in Puerto Rico are classified with hospitals in the Northeast.

that of the U.S. population than of all hospital patients. In some months, too few specimens may be eligible in certain age-sex categories to reach the total of 300 specimens. The monthly sample of 300 specimens was considered the largest number that many hospitals could routinely obtain while meeting the stratification requirements.

To ensure a sufficient number of specimens to meet the monthly quotas for each age-sex stratum despite the random deletion of specimens from the final monthly sample (see Random subsampling), 10 percent more eligible specimens are initially collected and stored for each age-sex category.

Random subsampling. Each month, 10 percent more specimens (for example, 110 specimens for 25–44-year-olds) are collected in each age-sex category than are required to meet the quota. Before HIV testing, but after encrypted codes have been assigned, 10 percent of the specimens collected for each age-sex category are deleted from the sample using a random number table or other random technique.

Methods: Data Linked to Specimens

After determining specimen eligibility, no information about the source of the specimens other than age, sex, race, clinical service, and month and year of venipuncture is retained in a manner that can be linked to the specimen. To minimize the likelihood of identifying individual persons through unique constellations of demographic or clinical characteristics, race is not specified for racial groups that constitute less than 10 percent of all patients at that hospital, age is not specified for persons older than 65, and specimens from obstetric patients younger than 16 years or older than 39 are not

used. No information is available about behavioral risk factors for HIV infection. After personal identifying information is removed from specimens, testing of specimens and analysis of data are done by personnel who had no contact with patients or patient records.

Methods: HIV Antibody Testing

Sentinel hospitals screen specimens for HIV-1 antibody by an enzyme immunoassay licensed by the Food and Drug Administration (FDA). Specimens repeatedly reactive in the screening assay are tested using an FDA-licensed Western blot kit either at CDC, Atlanta, or at one other reference laboratory. The presence or absence of each virus-specific band is recorded and reported to CDC. Specimens are considered HIV-1 seropositive if antibody bands are detected by Western blot for at least two of the three gene products: p24, gp41, and gp120/160 (12).

Interpretation of Findings

Sentinel hospitals constitute a principal serologic surveillance system of the Public Health Service for monitoring HIV infection across all age groups and across various levels and types of behavioral risk for HIV infection. Data from this surveillance system will contribute to understanding the demographics of HIV infection in the United States. Through the sentinel hospital network, trends in seroprevalence can be monitored in geographically dispersed urban areas with high, medium, and low seroprevalence. In addition, sentinel hospital data may be used to evaluate the risk of HIV contamination of medical wastes and to assess the potential exposure of health care workers to HIV-contaminated blood from patients not suspected of having HIV infection.

For all of these uses, the most appropriate interpretation of sentinel hospital data will require understanding of (a) the impact of the eligibility criteria for selecting specimens; (b) the “representativeness” of hospitals in the sentinel hospital surveillance system; (c) assumptions about the relationship of HIV seroprevalence in hospital patients to that in the catchment population of hospital; and (d) the relationship of the sentinel hospital seroprevalence surveys to other CDC HIV seroprevalence surveys.

Impact of the eligibility criteria. The use of eligibility criteria to select a subpopulation of all hospital patients for study is a critical feature of this surveillance system and distinguishes it from other studies of HIV seroprevalence in hospital patients (11, 13). The eligibility criteria are applied to the principal reason for the

patient's current hospital visit and not to all past or current medical conditions. Therefore, for example, an AIDS patient, an intravenous drug user (IVDU), or any other patient seen for pneumonia (an ineligible condition) would be classified as ineligible, but an AIDS patient or IVDU with a fractured leg or hospitalized for childbirth would be eligible.

In addition, the exclusion of repeat specimens limits the impact on seroprevalence findings that any one HIV-infected person can have from repeated hospital visits and supplements the diagnosis-based exclusion criteria. To recapitulate, the purpose of eligibility criteria is not to eliminate specimens from persons with HIV infections from the sample study, but to limit their overrepresentation, compared with all persons in the hospital catchment population.

Since these eligibility criteria are based upon incomplete knowledge of both the patient's illness as well as the full spectrum of illnesses associated with HIV, the absolute level of seroprevalence observed at a sentinel hospital should be interpreted with caution. On the other hand, because the same selection factors are applied to all patients at each sentinel hospital, the relative distribution of seroprevalence rates by age, sex, and race is likely to reflect those rates in the population served by each hospital. Likewise, the relative level of HIV seroprevalence between hospitals probably provides a reliable index of the relative HIV seroprevalence between hospital catchment populations. Furthermore, because the eligibility criteria are applied in the same manner over time, trends in HIV prevalence observed over time should reflect trends in HIV infection in these communities.

Representativeness. The principal objectives of sentinel hospital surveillance do not require inference to the "general population" of the United States or to standard geographic entities such as cities or metropolitan statistical areas. Therefore, the nonprobability sample of sentinel hospitals (14) is not a major drawback in attempting to meet those objectives. However, the absence of HIV seroprevalence data from any consistently studied population more nearly approximating the general population of the United States than sentinel hospital patients has led to sentinel hospital data being cited as estimates of rates of HIV infection in the U.S. population (15).

The paucity of more appropriate data for this purpose make it likely that sentinel hospital data will continue to be used in this way. Since probability methods were not used for the selection of hospitals, inference from sentinel hospital data to estimates of seroprevalence for the United States—if undertaken at all—can only be based upon statistical modeling on variables for which the dis-

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tribution across the United States is known, such as the AIDS cases reported by region or HIV-specific discharges at hospitals.

Principal assumptions. Different assumptions are implicit in the various uses of data from sentinel hospitals. The eligibility criteria represent an implicit assumption about the relationship between HIV infection and the use of hospital services. While AIDS and other late manifestations of HIV infection clearly lead to an increased need for hospital services, the extent to which earlier stages of HIV infection may do so as well is unclear. Data from active duty military personnel suggest that HIV-infected persons *do* seek care more frequently than uninfected persons before the recognition of HIV infection, but that the types of medical conditions for which this excess care is sought would generally constitute a basis for exclusion on the basis of the sentinel hospital eligibility criteria (16) (and personal communication from John McNeil and coworkers of the Walter Reed Army Institute of Research). Nonetheless, evaluation of the reasons for hospitalization by persons with unrecognized HIV infection remains an important area of investigation that will have a major impact on the interpretation of sentinel hospital data.

For analysis of trends in sentinel hospital HIV seroprevalence rates, the major assumption necessary is that the relationship between seroprevalence in the catchment population and seroprevalence among patients whose specimens are eligible for sentinel hospital surveillance remains constant over time; the quantitative relationship between seroprevalence in these two populations need not be determined. For analysis of the demographics of HIV infection, the major assumption is that biases inherent in the use of hospital patients as a sentinel population act in a similar manner across the subpopulations being examined—such as different age groups or racial groups—as well as across the sample of hospitals.

Relationship to other surveys. Most population subgroups now under active surveillance for HIV infection in the CDC family of seroprevalence surveys are characterized both by particular types and varying levels of risk for HIV infection and by a limited age-range of subjects. For example, groups at higher risk of exposure include intravenous drug users (17) and patients with sexually transmitted diseases (18). Low risk groups include prospective blood donors (19) and civilian applicants for military service (8), who are counseled against entry into either activity because of a history of high risk behavior. The least biased and most truly population-based survey in the CDC family of seroprevalence surveys is the survey of childbearing women (14). However, this survey includes only women who are sexually active, fertile, and not using birth control effectively. Among such women, it is further restricted to those who elect to carry their pregnancies to term and whose infants live long enough to have blood drawn for screening programs for metabolic diseases. The lack of bias associated with HIV seroprevalence estimates among childbearing women is therefore offset to some extent by the relatively narrow demographic range of the population to which the estimates apply and by the lack of knowledge of the relationship between HIV infection and fertility, fecundity, fetal demise, and early neonatal death.

The evaluation of HIV seroprevalence across all risk groups and age groups through this nationwide network of sentinel hospitals will contribute important information to integrate the age group-specific and risk group-specific findings from other sentinel surveillance surveys (20). In particular, the sentinel hospital surveillance system may contribute to more informed inference from findings of the survey among childbearing women, since the sentinel hospital study population includes a large and varied sample of women of reproductive age seen for both obstetric and non-obstetric conditions.

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